

**REMARKS**

The Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. Amendments to the Specification and Claims**

In the specification, the **Title** as been amended to better reflect the subject matter of the claims. No new matter is added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 1-41, 46, 48, and 56-57 are requested to be cancelled without prejudice. Claims 42, 45, and 47 are currently amended to advance prosecution of the application. Claims 58-66 are requested to be added. These amendments do not add new matter and entry thereof is respectfully requested.

After amending the claims as set forth above, claims 42-45, 47, 49-55, and 58-66 are now pending in this application.

**II. Claim Rejections – 35 U.S.C. § 112, second paragraph**

Claims 42-55 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly “being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” In particular, the Examiner has asserted that the scope of the claims is indefinite because the claims lack a “resolution step wherein the increased or decreased permeability induced by the candidate inhibitor is correlated with antiviral activity.” Further, claim 42 is alleged to be indefinite for reciting “a variant.” The Applicants respectfully traverse the rejection in view of the claim amendments and for the following reasons.

As amended, claim 42 and claim 58 recite a “method of screening for an inhibitor of HCV p7 protein.” The claims do not recite a “composition for treatment” or a “method of treatment.” Further, claim 42 and claim 58 recite “observing a decrease in the permeability in the p7-containing membrane, thereby identifying the inhibitor of HCV p7 protein.” As amended, claim 42 and claim 58 do not recite “variant.”

Therefore, one of skill in the art would fully recognize the metes and bounds of the claims. Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, for alleged “indefiniteness” are respectfully requested.

### **III. Claim Rejections – 35 U.S.C. § 112, first paragraph, “enablement”**

Claims 42-55 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. In particular, the Examiner asserts that the claims are not enabled because “Applicants have not shown that p-7 controls HCV infection by modulating membrane permeability.” The Applicants respectfully traverse the rejection in view of the claim amendments and for the following reasons.

Claim 42 and claim 58 recite a “method of screening for an inhibitor of HCV p7 protein.” The claims do not recite a “composition for treatment” or a “method of treatment.”

Further, one of skill in the art could practice the claimed method to identify an inhibitor of HCV p7 protein without having to undertake “undue experimentation.” For example, one of skill in the art would know how to perform the steps recited in the claims based on the specification and knowledge in the art, including:

- (a) incorporating a p7 protein into a membrane to create a p7-containing membrane;
- (b) contacting one or more components of the p7-containing membrane with a test compound;
- (c) comparing permeability of the p7-containing membrane...; and
- (d) observing a decrease in the permeability of the p7-containing membrane

The Examiner has asserted that “[r]ecent research shows that HCV p-7 mutants have decreased ability to cause infection *in vivo*[, but that] it is unclear whether the loss of infectivity is due to the decreased ability of the mutant p-7 protein to decrease membrane permeability.” Further, the Examiner has asserted that “Applicants’ working examples also fail to show a correlation between a compound[‘s] impact on p-7 permeability and HCV infectivity.”

However, it is respectfully noted that the present claims do not recite any step for which enablement requires a showing of a correlation between decreased permeability and decreased infectivity. The claims recite a “method of screening for an inhibitor of HCV p7 protein.” One of skill in the art could practice the claimed methods to obtain an inhibitor of HCV p7 protein without a showing of a correlation between decreased permeability and decreased HCV infectivity. As such, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement are respectfully requested.

**IV. Claim Rejections – 35 U.S.C. § 112, first paragraph, “written description”**

Claims 42-55 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. In particular, the claims are rejected for reciting a “p7 protein...variant.” As amended, the claims do not recite “variant.” As such, reconsideration and withdrawal of the rejection are respectfully requested.

V. **Conclusion**

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date

12/6/2005

By

M. Scott McBride

FOLEY & LARDNER LLP  
Customer Number: 22428

M. Scott McBride  
Attorney for the Applicants  
Registration No. 52,008  
Telephone: (414) 297-5529  
Facsimile: (414) 297-4900